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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/595,580

Applicant(s)

DOUGHERTY ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-53 and 61-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-53 and 61-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicants' arguments, filed 19 February 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-6, 8-53, and 61-70 are currently pending.

Rejections under 35 USC 102 and 35 USC 103 have been withdrawn in view of Applicant's response.

New claims 68-70 are withdrawn from consideration for being drawn to a non-elected invention. The originally elected invention was drawn to a computer implemented method for quantifying gene relatedness, which is not the same as computing a coefficient of determination.

Claim Rejections - 35 USC § 112

112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-53, and 61-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a new grounds of rejection based upon Applicant's amendments to the claims.

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In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able to quantify relative gene relatedness. For the reasons discussed below, this constitutes undue experimentation.

b) The specification provides examples for quantifying gene relatedness based upon comparison of observed gene expression levels and predicted gene expression levels. For example, at page 12 the specification teaches the following:

The system 402 responsible for expression of a particular gene can be represented as shown in FIG. 4. In the system 402, a set of observable inputs X_1 - X_m and a set of unknown inputs U_1 - U_n operate to produce an observed result, Y_{observed} (or simply Y). Some of the observable inputs X_1 - X_m can correspond to gene expression levels. For the sake of example, it is assumed that the internal workings of the system 402 are beyond current understanding. FIG. 5 shows a multivariate nonlinear model 502 for predicting the operation of the system 402. The model 502 is illustrated as comprising logic, but any multivariate nonlinear model can be used. The model 502 takes the observed inputs X_1 - X_m as inputs and provides a predicted output, Y_{pred} . In a model predicting gene expression, the inputs X_1 - X_m represent a set of predictive elements (e.g., gene expression levels, experimental conditions, or both), and Y represents the expression level of a predicted gene. The effectiveness of the multivariate nonlinear model 502 in predicting gene expression for the predicted gene can be measured to quantify the relatedness of the predicted gene and genes associated with the predictive elements. Measuring the effectiveness of the multivariate nonlinear model 502 can be accomplished by comparing Y_{pred} and Y_{observed} across a data set.

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However, these steps are not reflected in the instant claims and as written the claims are not enabled. In the instant claims, the relatedness of a gene to individual subset combinations is never measured. Therefore, how is relatedness measured in the instant claims? Step (b) appears to be a redundant step. Step (a) is already drawn to a nonlinear model in which gene expression is predicted. Furthermore, step (c) cannot be performed if data for all subsets is not included in the measurement.

Furthermore, the limitations of the non-linear model are not fully described such that one of ordinary skill in the art could make or use the model. Claim 12 recites a model in which data are divided into a training set and a test set. In some way, the nonlinear model is then generated via the training set. However, there are no steps set forth such that the test set is compared to the training set, typically necessary to establish a nonlinear model. In claim 15, a completely different nonlinear model is constructed from a predictive element. How is the model constructed from a predictive element. There are no steps such that one of ordinary skill in the art could make this nonlinear model.

c) The specification provides working examples of using the particular method to determine relatedness of a set of genes at page 28. However, the instant claims do not reflect those steps.

d) The invention is drawn to a method for predicting the relatedness of a set of genes by establishing a nonlinear model.

e) and g) The prior art provides no recognized model of a computer implemented method for quantifying relative gene relatedness using the steps of the instant invention.

f) The skill of those in the art of bioinformatics is high.

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112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-53, and 61-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 now recites “selecting a plurality of selected”. This is a redundant statement.

Clarification is requested.

Claim 1 is unclear in that there are no limitations on the non-linear model. What are the metes and bounds of the model such that one of skill in the art could construct such a model? Is the model a neural network or some other kind of nonlinear model?

Claim 15 recites “predictive element”. It is unclear from where the predictive element comes? Is it the subset combination in claim 1 or some other factor?

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

MARJORIE MORAN
PATENT EXAMINER

Marjorie G. Moran
6/10/04

June 10, 2004

Lori A. Clow, Ph.D.

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Lori A. Clow